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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,279	09/30/2002	Jeffrey C. Leung	013341.000020	5693
24239	7590	12/30/2005	EXAMINER	
MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 12/30/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/065,279	<b>Applicant(s)</b> LEUNG ET AL.	
	<b>Examiner</b> Tuan V. Nguyen	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 12/08/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 37-57, 59, 61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36, 58 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 and 16 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/29/05, 11/08/04, 06/03/03, 07/15/03</u> | 6) <input type="checkbox"/> Other: _____   |

**DETAILED ACTION**

***Election/Restrictions***

1. Personal Interview between Applicant's representatives and Examiner was held on December 8, 2005. Election/Restrictions mailed out to Mr. Michael Johnston on 10/04/2005 was discussed. Examiner decided to withdraw the Election/Restrictions mailed out on 10/04/2005. Mr. Johnston, Applicant's representatives, and Examiner were agreed on the details of a new Election/Restriction. The details are as follows:

Group I, claims 1-36, 58, and 60, drawn to the barbs having certain cut parameters.

Group II, claims 37-43, drawn to the barbs have a configuration of a corrugated barb underside.

Group III, claims 44-50, drawn to the barbs have a configuration of a arcuate barb base.

Group IV, claims 51-57, drawn to the barbs have different size from each other.

Canceled claims 59, 61, and 62.

2. A telephone call was made to Mr. Michael Johnston on December 9, 2005 to discuss the above restriction requirement. The result was a provisional election was made without traverse to prosecute the invention of Group I, claims 1-36, 58,

and 60. Claims 37-43, 44-50, and 51-57 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant wishes canceled claims 59, 61, and 62. Affirmation of this election must be made by applicant in replying to this Office action. Mr. Michael Johnston stated that in making the foregoing election in response to the above election/restrictions requirement, applicant reserves the right to file a divisional application containing those claims directed to the non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
4. Interview Summary (PTOL-413) is attached with the Office Action for reference.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-3, 5-9, 0-12, 14-18, 19-21, 23-27, 28-30, 32-36, and 58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buncke (U.S. 5,931,855).
7. Referring to claims 1-3 and 9, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col 8, lines 12-19). Buncke fails to disclose the barb cut angle ranging from about 140 degrees to about 175 degrees. It would have been an obvious to a person of ordinary skill in art to derive the barb cut angle from the depth and spacings parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a barb cut angle ranging from about 140 degrees to about 175 degrees, because applicant has not disclosed that the umbrella structure shape provides an advantage, is used for a particular purpose, or solves a stated problem.

8. Referring to claims 5-8, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col 1, lines 20-25).
9. Referring to claims 10-12 and 18, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col 8, lines 12-19).
10. Referring to claims 14-17, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col 1, lines 20-25).
11. Referring to claims 19-22 and 27, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col 9, lines 4-7). Buncke further discloses the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col 8, lines 12-19). Buncke fails to disclose the barb cut length and the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2. Here it is noted that Buncke disclose the spacings between barbs therefore the barb cut length is felt into this range. It would have been an obvious to a person of ordinary

skill in art to derive the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2 from the spacings and barb cut depth parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2, because applicant has not disclosed that the umbrella structure shape provides an advantage, is used for a particular purpose, or solves a stated problem.

12. Referring to claims 23-26, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col 1, lines 20-25).
13. Referring to claims 28-30 and 36, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barb cut distance or barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col 8, lines 12-19).

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14. Referring to claims 32-35, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col 1, lines 20-25).
15. Claim 58, it is rejected for the same reason as claim 1 combined with 10, 19, and 28.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
18. Claims 4, 13, 22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and further in view of Leung et al (U.S. 6,599,310).



19. Referring to claim 4, Buncke discloses the invention substantially as claimed except for the barbs are configured in at least two set, each set having a barb size different from the barb size of the other set. Leung et al disclose (see Fig 1) a barbed suture having two set of barbs, wherein each set having a barb size different from the barb size of the other set (see col 8, lines 53-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the different barbed size on the suture, as disclosed by Leung et al, to incorporate into the device, as disclosed by Buncke because this will be used in tissue repair with different layer structure.
20. Referring to claims 13, 22, and 31, they are rejected for the same reason as claim 4.

### ***Double Patenting***

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.

Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claim 58 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 22 of copending Application No. 10/065280 (Pub. No. US 2004/0060410). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.
23. Claim 60 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of copending Application No. 10/065280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.
24. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen  
December 19, 2005



**ANHTUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

12/22/05